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| APPLICATION 1 | NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------|----------------------|----------------|--------------------------|---------------------|------------------|
| 10/527,091 | | 03/09/2005 | You Sup Chung | 1751-374 | 2766 |
| 6449 | 7590 | 05/22/2006 | | EXAM | INER |
| | VELL, FIG | G, ERNST & MAN | MORRIS, P. | MORRIS, PATRICIA L | |
| SUITE 8 | • | · · · | | ART UNIT | PAPER NUMBER |
| WASHIN | WASHINGTON, DC 20005 | | | 1625 | |
| | | | DATE MAIL ED: 05/22/2006 | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Application No. | Applicant(s) | | | |
|--|--|---|---|--|--|--|
| Office Action Summary | | 10/527,091 | CHUNG ET AL. | | | |
| | | Examiner | Art Unit | | | |
| | | Patricia L. Morris | 1625 | | | |
| | The MAILING DATE of this communication app | | | | | |
| Period fo | or Reply | | | | | |
| WHIC - Exte after - If NC - Failu Any | ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DATE of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. Operiod for reply is specified above, the maximum statutory period was to reply within the set or extended period for reply will, by statute, reply received by the Office later than three months after the mailing ed patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim will apply and will expire SIX (6) MONTHS from , cause the application to become ABANDONE | N. nely filed the mailing date of this communication. D (35 U.S.C. § 133). | | | |
| Status | | | | | | |
| 1)🛛 | Responsive to communication(s) filed on 24 M | arch 2006. | | | | |
| · · · · · · · · · · · · · · · · · · · | This action is FINAL . 2b) This action is non-final. | | | | | |
| 3)□ | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | |
| | closed in accordance with the practice under E | x parte Quayle, 1935 C.D. 11, 45 | 33 O.G. 213. | | | |
| Disposit | ion of Claims | | | | | |
| 5)□ 6)⊠ 7)□ | Claim(s) 1-11 is/are pending in the application. 4a) Of the above claim(s) 10 and 11 is/are with Claim(s) is/are allowed. Claim(s) 1-9 is/are rejected. Claim(s) is/are objected to. Claim(s) are subject to restriction and/o | drawn from consideration. | | | | |
| Applicati | ion Papers | | | | | |
| 10)🛛 | The specification is objected to by the Examine The drawing(s) filed on <u>09 March 2006</u> is/are: Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct The oath or declaration is objected to by the Examine | a)⊠ accepted or b)⊡ objected to drawing(s) be held in abeyance. See ion is required if the drawing(s) is obj | e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d). | | | |
| Priority (| under 35 U.S.C. § 119 | | | | | |
| 12) □ a)l | Acknowledgment is made of a claim for foreign All b) Some * c) None of: 1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the priority application from the International Bureau See the attached detailed Office action for a list | s have been received. s have been received in Applicati rity documents have been receive u (PCT Rule 17.2(a)). | on No ed in this National Stage | | | |
| 2) 🔲 Notic | t(s) e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 4) | (PTO-413) ate atent Application (PTO-152) | | | |
| | r No(s)/Mail Date | 6) Other: | 2.0 rippinoution (1.10-102) | | | |

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DETAILED ACTION

Claims 1-9 are under consideration in this application.

Claims 10 and 11 are held withdrawn from consideration as being drawn to nonelected subject matter 37 CFR 1.142(b).

Election/Restrictions

Applicant's election without traverse of Group I in the reply filed on March 24, 2006 is acknowledged.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-9 are rejected under 35 U.S.C. 102(a) and/or (e) as being anticipated by Joshi et al. (US 2003/0176706).

Joshi et al. disclose the instant process. Note the reaction scheme in sections [0009] and [0014]. Hence, the instant process is deemed to be anticipated therefrom.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Joshi et al.

Joshi et al.. teach the instant process of reacting R,S-amlodipine with L- (+)-tartaric acid in dimethyl sulfoxide, filtering off the resulting precipitate and precipitating (S)-(-)-amlodipine-hemi-L-tartrate-monohydrate with methylene chloride and subsequent basification to form the S- (-)-amlopidine isomer. Note the reaction scheme in sections [0009] and [0014].

One having ordinary skill in the art would have been motivated to employ the process of the prior art with the expectation of obtaining the desired product, because he would have expected the analogous starting materials to react similarly. It has been held that application of an old process to a new and analogous material to obtain a result consistent with the teachings of the art would have been obvious to one having ordinary skill.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3 contains the trade name amlodipine. Where a trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trade name cannot be used properly to identify any particular material or product. A trade name is used to identify a source of goods, and not the goods themselves. Thus, trade name does not identify or describe the goods associated with the trade name. In the present case, the trade name is used to identify/describe a chemical structure and, accordingly, the identification/description is indefinite. Only the IUPAC name properly defines chemical structures.

Specification

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia L. Morris whose telephone number is (571) 272-0688. The examiner can normally be reached on Mondays through Fridays.

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The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia L. Morris Primary Examiner Art Unit 1625

plm May 17, 2006